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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/151,885	09/11/1998	JAMES C. COSTIN	98-WL-1	8455

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 09/20/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/151,885

Applicant(s)

COSTIN, JAMES C.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 7-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. Amendment D filed June 18, 2002 has been received and entered into the record.
2. Claims 7-17 are pending in the case.
3. The text of those sections of title 35, U. S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 13-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The newly added Claims 13-17 set forth information in the claims that is not supported in the instant specification. Claims 13 and 17, which indicates that the epithelial cells thereof are epithelial cells other than human uroepithelial cells; Claims 14 and 17, which indicates that the microorganisms thereof are microorganism other than urine isolates of *escherichia coli*; Claims 15 and 17, which discloses that the buccal epithelial cells thereof are buccal epithelial cells other than human buccal epithelial cells; and Claims 16 and 17, which discloses that the microorganisms thereof are microorganisms other than oral isolates of *candida albicans*, all include limitations of the instantly Claimed invention that is not supported in the instant specification. Hence, the newly recited Claims 13-17 set forth new mater, which is improper under the 1<sup>st</sup> paragraph of 35 USC 112.

***Claim Rejections - 35 USC § 102***

6. Claims 7 and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Blenkarn (Surgical Res. Commun., Vol. 2, pp. 149-155 (1987)) for the reasons already of record on page 4 of the Office Action mailed December 12, 2001.

7. Applicant's arguments filed June 18, 2002 have been fully considered but they are not persuasive. Applicant argues against the rejection on the grounds that the Blenkarn reference discloses taurolidine ability to prevent adhesion of microorganisms to epithelial *surfaces* whereby the instant claims disclose reducing the adherence of microorganisms to epithelial *cells*. This argument is not persuasive because one of ordinary skill in the art would know that reference to "epithelial" refers to a membranous cellular tissue that covers a free surface or lines a tube or cavity of an animal body and serves especially to enclosed and protect the other parts of the body. "Epithelial surfaces" and "epithelial cells" refers to the same body tissue. Applicants also argue that Blenkarn does not anticipate instant Claim 9 because Claim 9 discloses urine isolates of Escherichia coli and the Blenkarn does not mention urine. However, this argument is not persuasive since Escherichia coli is the same no matter how the microorganism is isolated. Accordingly, the rejection of Claims 7 and 9 under 35 U.S.C. 102(b) as being anticipated by the Blenkarn reference is maintained.

8. Claims 7-9, 11 and 12 stand rejected under 35 U.S.C. 102(b) as being anticipated by Gorman et al (Journal of Pharmacy and Therapeutics, Vol. 12, pages 293-399 (1987)) for the reasons already of record on page 5 of the Office Action mailed December 12, 2001.

9. Applicant's arguments filed June 18, 2002 have been fully considered but they are not persuasive. Applicant appears to argue against the rejection of the claims on the ground that the claims are broader than the disclosure of the Gorman et al reference. This argument is not persuasive. The rejection is deemed proper as long as the Gorman et al patent discloses information that is used for the rejection of claims which fall within the scope of the claimed invention. Accordingly, the rejection of Claims 7-9,

11 and 12 under 35 U.S.C. 102(b) as being anticipated by the Gorman et al reference is maintained.

***Claim Rejections - 35 USC § 103***

10. Claim 10 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al (Journal of Pharmacy and Therapeutics, vol. 12, pages 393-399 (1987)) in view of Blenkarn (Surgical Res. Commun., Vol. 2, pp. 149-155 (1987)) for the reasons already of record on pages 5 and 6 of the Office Action mailed December 12, 2001.

11. Applicant's arguments filed June 18, 2002 have been fully considered but they are not persuasive. Applicant argue against the rejection of the claim on the ground that the references used to reject the claims fail to indicate taurolidine being used to reduce the adherence of *staphylococcus saprophyticus* to epithelial cells. Applicant also argues that no generalism with regard to *Staphylococcus* and taurolidine is to be gleaned from Blenkarn alone. However, these arguments are not persuasive since the Blenkarn reference shows that taruolidine is effective against many microorganisms, including staphylococcus aureus. See the first sentence in the abstract wherein the Blenkarn reference discloses that taurolidine has a uniquely broad spectrum of antibacterial and antifungal activity. This statement is further evidenced in the Fujiwara et al patent – US Patent No. 5,595,742 - (not used in the rejection) which discloses an antimicrobial agent that can be applied widely to bacterial of the genus *Staphylococcus* that include *Staphylococcus epidemidis*, *Staphylococcus saprophyticus*, *Staphylococcus aureus* and Methicillin Resistant *Staphylococcus aureus* (see column 2, 5<sup>th</sup> paragraph). This passage of the Fujiwara et al patent is only cited to show that, which is known in the art, which is taurolidine possessing a broad spectrum of antibacterial activity where *Staphylococcus aureus* is given as an example as indicated in the Blenkarn reference would include *Staphylococcus saprophyticus* as a member of the group of bacterial where taurolidine would be effective as an antibacterial agent. Accordingly, the rejection of Claim 10 under 35 U.S.C. 103(a) as being unpatentable over the Gorman et al and Blenkarn references is maintained.

***Summary***

12. All the pending claims are rejected.

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

***Examiner's Telephone Number, Fax Number, and Other Information***

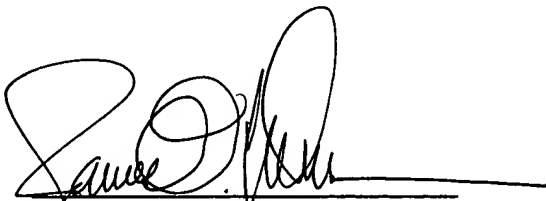
14. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at [www.uspto.gov](http://www.uspto.gov) and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (703) 308-4624. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

*E. White*  
E. White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600